

Translation

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P03-123	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2003/015510	International filing date (day/month/year) 04 December 2003 (04.12.2003)	Priority date (day/month/year) 06 December 2002 (06.12.2002)
International Patent Classification (IPC) or national classification and IPC A61K 31/05, 9/10, 47/12, 47/24, A61P 23/00, 25/20		
Applicant OTSUKA PHARMACEUTICAL FACTORY, INC.		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>7</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand 02 July 2004 (02.07.2004)	Date of completion of this report 14 December 2004 (14.12.2004)
Name and mailing address of the IPEA/JP	Authorized officer

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/015510

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

- ☐ international search (under Rules 12.3 and 23.1(b))
☐ publication of the international application (under Rule 12.4)
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ The international application as originally filed/furnished

☒ the description:

pages _____ 1-44 _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ the claims:

pages _____ 2-4,8,9,11-13,15-17,19,20,24,25,27-29,31,32 _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ 1,5,7,18,21,23,33,34 received by this Authority on 30 November 2004 (30.11.2004)

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☒ the claims, Nos. _____ 6,10,14,22,26,30 _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of these sheets may be marked "superseded"

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

T/JP03/15510

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-5, 7-9, 11-13, 15-21, 23-25, 27-19, 31-34	YES
	Claims		NO
Inventive step (IS)	Claims	1-5, 7-9, 11-13, 15-21, 23-25, 27-19, 31-34	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-5, 7-9, 11-13, 15-21, 23-25, 27-19, 31-34	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: JP, 2002-179562, A

Document 2: WO, 01/97779, A2

Document 3: WO, 00/10531, A1

Document 4: WO, 01/01960, A1

<The subject matter of claims 1-5, 7-9, 11-13, 15-21, 23-25, 27-29 and 31-34>

None of the documents cited in the ISR discloses the inventions relating to claims 1-5, 7-9, 11-13, 15-21, 23-25, 27-29 and 31-34, and they appear to be novel and to involve an inventive step.

In particular, none of documents 1-4, which are found to be the most relevant prior art documents, discloses fat emulsions to which a local anesthetic is added as needed, comprising emulsions propofol, an oily component, and an emulsifier, and further comprising, as a stabilizer, (a), (b), (c) or (d) described in claim 1.